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SERIAL NUMBER 0721185252	FILING DATE 01/22/89	FIRST NAMED INVENTOR HESSEL	ATTORNEY DOCKET NO.
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WASHINGTON, D.C. 20005

EXAMINER

GILMORE, E

ART UNIT
336

PAPER NUMBER

13

DATE MAILED: 11/20/89

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 09/14/89 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire _____ month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 21-23 AND 26 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 21-23 AND 26 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable, ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved, ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Applicant's amendment filed September 10, 1989, has been entered into the record.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The word "about" merely indicates an approximation which does not describe applicant's device in exact terms. For example, applicant discloses, at page 12, lines 8-9, that the width of the condom like device of his invention is "between about 55 mm and about 85 mm". Such a description is not in full and exact terms. Applicant has not defined the term "hand feel", at page 8, paragraph 1.

Claims 21-23 and 26 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention now claimed.

The specification does not support a means for retaining the closed end of the device within a vagina juxtaposed to the cervix. Applicant discloses that the elastic ring which maintains the device in the vagina is placed in the vicinity of the uterus, which means that the ring can be located anywhere in the vagina near the uterus. Applicant claims that the means for retaining the closed end of the device in the vagina is juxtaposed to the cervix. Juxtaposed to the cervix means to be next to the cervix, which is distinguishable from near the uterus.

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Claims 21-23 and 26 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 21-23 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. patent no. 4,735,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed "means for retaining" reads on the claimed patented second ring and the practice of making prophylactics from polyethylenes and polyurethanes is well known in the contraceptive art.

Dyck et al. disclose, at column 2, that prophylactics can be made from polyethylene, polyvinyl alcohol, and thermoplastic polyurethanes.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102

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of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-23 and 26 are rejected under 35 U.S.C. § 103 as being unpatentable over Graham in view of Dyck et al.

Graham discloses the device substantially as claimed. Graham discloses a tubular device made from a thin-walled flexible tube having open and closed ends, an outwardly extending collar-shaped means which radially stretches the open end, and a second ring connected to the tube. Specifically, applicant's claimed "first elastic ring" reads on element 8 of Graham because as seen from Figures 1-3, the first ring has a diameter larger than the diameter of the tube 4. Applicant's claimed means for retaining reads on element 1 of Graham because element 1 is essentially located at the closed end of the tube. Although the specific material used by Graham is soft rubber, Graham does not limit himself to only using soft rubber in that he teaches generally using an elastic flexible material (see page 1, line 39). However, Graham does not disclose making his invention from polyethylenes, polyurethanes, and derivatives thereof.

Dyck et al. disclose, at column 2, that prophylactics can be made from polyethylenes and thermoplastic polyurethanes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the Graham device from a group consisting of polyethylenes and polyurethanes, as taught by Dyck et al.

Applicant's arguments filed September 19, 1989, have been fully considered but they are not deemed to be persuasive.

Applicant argues that his device is distinguishable from the Graham invention because the Graham device is not held firmly in place near the cervix. However, applicant has not disclosed that his device is held firmly in place near the cervix. Applicant has merely disclosed, at page 14, second paragraph, that the means for retaining his device in the vagina is placed in the vicinity of the uterus.

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Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Barnerico Gilmore at telephone number (703) 557-3125.

Barnerico Gilmore

Barnerico Gilmore
November 20, 1989


STEPHEN C. PELLEGRINO
PRIMARY EXAMINER
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